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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: WILLIAM R. DUBRUL and RICHARD E. FULTON Application No.: Not Assigned Yet Filed: Concurrently Herewith Title: DILATING AND SUPPORT APPARATUS WITH DISEASE INHIBITORS AND METHODS FOR USE	Attorney Docket No.: ARTM 1008-5 Examiner: Not Assigned Yet Group: Not Assigned Yet

BOX PATENT APPLICATION
Assistant Commissioner for Patents
Washington, D.C. 20231

PRELIMINARY AMENDMENT

Before the first action in this divisional application under 37 CFR 1.53 (b), please amend this application as follows.

In The Specification

At page 1, please delete the 4 lines under the section entitled **"Cross reference to related application"** and substitute the following:

--This application is a division of U.S. patent application No. 09/298,279 filed April 23, 1999, which claims the benefit of the following provisional patent applications: application No. 60/083, 178 filed April 27, 1998; application No. 60/095,106 filed August 3, 1998; and application No. 60/115,548 filed January 12, 1999, the disclosures of which are incorporated by reference.—

At page 19, please delete the first line (page line 5) and substitute the following: --provisional submission Serial No. 60/121,640.

The tubular braid may be coated with a material so that it may have no porosity or variable porosity within the individual filaments of the braid. With one technique the braid was expanded from its original small diameter by sliding a mandril into the tubular braid. Once the braid is expanded, a liquid thermoset elastomer including, but not limited to silicone rubber, latex rubber, etc. or thermoplastic material including, but not limited to

polyurethane was coated via a spray, dip, brush or other method. When the material cured, the mandril was removed and the tubular braid could be pulled on both ends (put into compression) and the tubular braid would go back to its original diameter. This is important for several reasons; the method described here allows the material to be applied within the filaments instead of over the filaments. This decreases the overall diameter of the tubular braid significantly as opposed to putting a covering over it. Further, the integrity of the material in between the filaments as opposed to over the filaments is increased because as the expandable channel is pushed forward, the material is hidden within the braid and hence doesn't see the forces of the tissue against it. Using a covering over the braid, the forces during the pushing are directly transmitted to the covering over the braid. Even further, the reliability and cost to manufacture are greatly improved. Even further and of extreme import is the fact that using a liquid that cures or a thermoplastic covering that is melted into the braid as opposed to covering it allows for varying the porosity along the tubular braid. This is extremely important in those cases where variable porosity is desired such as when the device is being used for a filter such as in the case of trapping emboli that are loosened during interventional vascular procedures to name one instance. In this case the emboli could travel into the device where the pore size is large, but not pass through the device where the pore size is less. The emboli could then be removed once the device is un-deployed.

Several different types of tubular braid were coated with silicone rubber elastomer. In one case, the braid was expanded to some diameter greater than the relaxed and smaller diameter. This was accomplished using a Teflon mandril. With the tubular braid in this somewhat expanded condition, the assembly was coated with liquid silicone rubber. When it dried, the assembly could be elongated by putting the system into tension so that the smaller original diameter was achieved again. It could then be put into compression and thusly shortened so that it would expand and the braid was covered so that there could be no holes in between the filaments of the braid. Further, the overall diameter of the tubular braid was not increased except for maybe .0001". Even further, filter devices were made whereby the silicone rubber was sprayed or painted onto the tubular braid when it was in the deployed/expanded condition. Once dried, the assembly could be un-deployed and then re-deployed with ease and without any holes between the

filaments. Lastly, tubular braids were coated as described above with only partial coating to create variable porosity along the braid. Even further, the totally coated tubular braid was easy to puncture so that variable porosity was achieved as well.

Producing a roughened surface on the film within the braided devices is easily accomplished in the manufacturing environment. One such way is to create bubbles in a liquid slurry of the polymer prior to its solid curing. Another might be the addition of dissolvable crystals to the surface of the liquid polymer prior to its cure. These dissolvable crystals could then be removed (washed off) after curing of the polymer.

The assembly of tube, mandril and braid is—.

In The Claims

Please cancel claims 1-25 and add claims 26-55 as follows.

26. (New) A method for dispensing an agent into body tissue defining a passageway comprising:

positioning a porous tubular mesh, comprising a contact-dispensable agent, at a target site within a passageway of a body;

expanding the tubular mesh against the body tissue by a radially-expandable element within the tubular mesh causing the tubular mesh to make intimate contact with the body tissue; and

dispensing the agent from the tubular mesh into the body tissue.

27. (New) The method according to claim 26 wherein the expanding step is carried out using a balloon.

28. (New) The method according to claim 26 further comprising:
selecting an absorbent fiber tubular mesh;
selecting the agent; and
applying the agent to the absorbent fibers of the tubular mesh prior to the positioning step.

29. (New) The method according to claim 26 wherein the dispensing step is carried out as a result of the expanding step.

30. (New) The method according to claim 26 wherein the dispensing step is carried out using iontophoresis.

31. (New) The method according to claim 26 wherein the positioning step is carried out using an axially-compressible and radially-expandable porous tubular braid as the porous tubular mesh.

32. (New) The method according to claim 26 wherein the positioning step is carried out using a porous tubular mesh which is not bioabsorbable.

33. (New) The method according to claim 26 wherein the positioning step is carried out using a catheter shaft, and further comprising the steps of releasing the tubular mesh at the target site and removing the catheter shaft from the passageway.

34. (New) A method for placing an endovascular structure at a target site within a passageway of the body comprising:

positioning an inflatable balloon, located at a first position along a catheter shaft of a catheter device, at a target site within a body passageway;

inflating the balloon at the target site;

deflating the balloon;

moving the catheter shaft through the passageway so to displace the balloon from the target site and position an axially-compressible, radially-expandable, tubular braid scaffolding at the target site;

expanding the tubular braid scaffolding against the wall of the passageway at the target site; and

removing the catheter shaft from the passageway.

35. (New) The method according to claim 34 wherein the expanding step is carried out using a self-expanding scaffolding.

36. (New) The method according to claim 34 wherein the expanding step comprises axially compressing the scaffolding.

37. (New) The method according to claim 34 further comprising the step of dispensing an agent into the target site after the expanding step.

38. (New) The method according to claim 34 further comprising releasing the scaffolding from the catheter shaft after the expanding step.

39. (New) A method for stabilizing an indwelling catheter at the exit site of the body comprising:

passing the distal end of a catheter through an exit site of the body so the proximal end of the catheter remains outside of the body;

positioning an axially-compressible, radially-expandable, tubular braid scaffolding at the exit site, the scaffolding secured to the catheter; and

securing the catheter in place at the exit site by placing the scaffolding in an axially-compressed, radially-expanded condition so the scaffolding presses against the exit site.

40. (New) The method according to claim 39 further comprising selecting a catheter having scaffolding made of a bioabsorbable material.

41. (New) A method for modifying a radially-expandable endovascular tubular braid structure comprising:

applying a material in a flowable state to the interstitial pores of a radially-expandable endovascular tubular braid structure;

curing the material to form a membrane at least within the coated interstitial pores.

42. (New) The method according to claim 41 wherein the applying step is carried out using a solvent as the material.

43. (New) The method according to claim 41 wherein the applying step is carried out using and thermoplastic materials as the material.

44. (New) The method according to claim 41 wherein the applying step is carried out by at least a chosen one of casting, spraying and dipping.

45. (New) The method according to claim 41 further comprising the step of at least partially radially expanding the tubular braid prior to the applying step.

46. (New) The method according to claim 41 wherein the applying step is carried out using a material that creates an elastic membrane upon curing.

47. (New) The method according to claim 41 wherein the applying step is carried out using a material that creates an inelastic membrane upon curing.

48. (New) The method according to claim 41 further comprising selecting a chosen porosity for the membrane and acting on the material to achieve a chosen porosity.

49. (New) The method according to claim 48 wherein the material acting on step is carried out as a part of at least one of the applying and curing steps to achieve said chosen porosity.

50. (New) The method according to claim 48 wherein the material acting on step comprises perforating the membrane after the curing step to achieve said chosen porosity.

51. (New) The method according to claim 41 wherein the applying step is carried out using at least one of dissolvable crystals and bubbles to roughen the surface of the cured membrane.

52. (New) The method according to claim 41 further comprising selecting at least one of polyester, polyethylene, polyurethane, silicone, or poly(ethylene terephthalate) for the membrane.

53. (New) The method according to claim 41 wherein the applying and curing steps are carried out a manner to create a tubular braid structure suitable for removing particulate from a blood vessel.

54. (New) A radially-expandable endovascular tubular braid structure made according to the method of claim 41.

55. (New) A method for modifying a radially-expandable endovascular tubular braid structure comprising:

applying a material in a flowable state to the interstitial pores of a radially-expandable endovascular tubular braid structure;

the applying step being carried out using a material that creates an elastic material upon curing;

curing the material to form an elastic membrane at least within the interstitial pores;

selecting a chosen porosity for the membrane; and

acting on the material to achieve the chosen porosity.

REMARKS

Claims 26-55 remain in this case.

Claims 26-40 of this divisional application correspond to restricted-out method claim 34-41, 47-51, and 55-56 of the parent patent application, respectively.

Method claims 41-54 are newly added. They are directed to methods discussed at p. 22, lines 11-22 and further discussed in provisional patent application No. 60/121,640, specifically referred to thereat. A copy of the '640 application is attached to this preliminary amendment for the Examiner's convenience. The above amendments to the specification are taken from p. 19, line 34-p. 28 line 26; p. 21, line 25-line 37; and p. 14, line 9-line 13 of the '640 application.

Although the words "incorporated by reference" was not used by **the *pro se* applicant** of the '279 parent application, it is clear that the applicant was making specific reference to the provisional patent application for the teachings of that provisional patent application relating to the method for coating the interstitial pores of the tubular braid and thus incorporated those teachings into the '279 application by such reference. Applicant understands that the entire disclosure of the '640 application was not incorporated by reference; however applicant submit that the specific reference to the specific manufacturing technology was intended to and acted to incorporate that material by reference.

Discussion of Incorporation By Reference

Incorporation by reference into a patent application of written matter found in other patents or printed publications is permitted "for economy, amplification, or clarity of exposition, by means of an incorporating statement clearly identifying the subject matter which is incorporated and where it is to be found." *In re De Seversky* 177 USPQ 144, 146 (CCPA 1973).

The "general incorporation of a U.S. patent by reference in appellant's specification is sufficient to indicate what is likely to be known by persons of ordinary skill in the art." *Ex parte Raible,* 8 USPQ2d 1709-1710 (BPAI 1988). "The issue of compliance with the description requirement, however, is another matter entirely.... The function of the description requirement is to ensure that the applicant had possession, as of the filing date of his application, of the specific subject matter later *claimed* by him. It

is required that the specification describe the invention sufficiently for those of ordinary skill in the art to recognize that the applicant invented the subject matter he now claims....The purpose of incorporation by reference in an application of matter elsewhere written down is for economy, amplification, or clarity of exposition, by means of an *incorporating statement clearly identifying the subject matter which is incorporated and where it is to be found.*" *Ex parte Raible* at 1710.

Using the words "incorporated by reference" will of course be sufficient to incorporate the reference into the patent application. The Manual for Patent Examining Procedure (MPEP) states "Mere reference to another application, patent or publication is not an incorporation of anything therein into the application containing such reference for the purpose of the disclosure required by 35 USC 112, first paragraph. *In re De Seversky, 474 F.2d 671,* 177 USPQ 144, 146 (CCPA 1973)." However, *De Seversky* is a situation in which a continuation in part patent application simply referred to a prior application for priority purposes; the patent application made no other references to the disclosure of the prior application and did not specifically incorporate the prior application by reference. The court held that the mere reference to a prior application for priority purposes was not sufficient to incorporate the prior application by reference.

In this case the ***pro se* applicant** made the following statement in U.S. patent application No. 09/298, 279: "Further, the inventors of the instant invention have disclosed a method of coating the interstitial pores of the tubular braid without adding to the overall wall thickness of the tubular braid. This manufacturing invention is disclosed in pending provisional submission Serial No. 60/121,640." This statement from the '279 application fulfills the stated factor of ensuring that the applicant had possession of the specific manufacturing method invention described in the '640 application. Therefore, those portions of the '640 provisional patent application relating to the method of coating the interstitial pores of the tubular braid have been properly incorporated by reference into the '279 application; to hold otherwise would elevate form over substance and would unfairly create a trap for the *pro se* applicant. Accordingly, the above amendments to the specification involve no new matter.

Applicant submits that the application is in condition for allowance and action to that end is urged. If the Examiner believes a telephone conference would aid the prosecution of this case in any way, please call the undersigned at (650) 712-0340.

Respectfully submitted,

Dated: 12 February 2001.

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